REMARKS/ARGUMENTS

Applicant has considered comments presented in the Office action of August 11, 2006, and presents the following remarks in response.

CURRENTLY PENDING CLAIMS. Claims 1-53, 89-106, and 123-125 are currently pending, of which independent claims 1, 28, and 89 are each amended hereby. Claims 54-88 and 107-122 remain withdrawn from consideration.

AMENDMENTS TO THE SPECIFICATION. The specification is hereby amended, as set forth above, to correct certain typographical errors regarding three reference numerals included in FIG. 19.

With regard to the paragraph that starts on page 19, line 11 and FIG. 19 that is described therein, the plain language of the paragraph and the clarity of the identified figure provide full support for the amendment: First, "line 1526" on page 19, line 21, clearly should be stricken and replaced with – line 1528 – because, on FIG. 19, the numeral 1528 clearly marks a line that "extend[s] from the most superior aspect 1513 of the neck 1512". Specification at page 19, lines 21-22. Second, "most inferior aspect 1528 of the neck 1512" at page 19, lines 22-23, clearly should be stricken and replaced with – most inferior aspect 1526 of the neck 1512 –. At FIG. 19, the numeral 1526 marks the lower most portion *(i.e.*, the "most inferior aspect") of the neck, which is identified by the numeral 1512.

With regard to the paragraph that starts at page 19, line 27, and FIG. 19 that is used to describe the method displayed in FIG. 20, again, the plain language of the paragraph and the clarity of the figure provide full support for the amendment. Here, "line 1526" at page 20, line 4, should be stricken and replaced with – line 1528 –, based on the same reasoning set forth above with respect to the amendment at page 19, line 21.

In view of the recited support for the specification amendments, applicant respectfully submits that no new matter has been added hereby.

AMENDMENTS TO THE CLAIMS.

The three independent claims are amended identically in the constructing step of each, as follows: The phrase "an analysis of anatomical biomechanical axes of the joint" is stricken and re-inserted earlier as the first of two elements used in constructing the three-dimensional model. The second element used is the surgical navigation system, which is more particularly described by the substitution of the phrase "based on" with the phrase –to mark–. Support for this amendment can be found in the specification at page 11, lines 29-30. The constructing steps of the amended claims are further amended to recite that the surgical navigation system is used without requiring a scan. Support for this amendment can be found in the specification from page 11, line 22 to page 14, line 29, where applicant sets forth a variety of embodiments of the inventive method.

The specification at page 15, lines 21-22, further supports the above described claim amendments with regard to scans by stating that "[t]he model can also be compared to pre-operative scans of various types, such as x-rays." In order for the comparison of the model to a scan to make sense, the three-dimensional model constructed in the context of the present invention as claimed must not be based on a scan.

In view of the recited support for the claim amendments, applicant respectfully submits that no new matter has been added hereby.

OBJECTION TO DRAWINGS UNDER 37 C.F.R. §1.121(d). The Office action at page 3 thereof objected to the drawings for allegedly not "show[ing] every feature of the invention specified in the claims." In particular, the Office action suggested that the claim limitations (1) "determining joint range of motion of the joint" and (2) "determining stability of the joint" are not set forth in the drawings as filed.

Applicant respectfully traverses this objection. As to the first limitation, FIG. 3 includes block **308**, which is labeled "Virtual Trial." The specification at page 11, lines 1-3, recites: "The look ahead or virtual trial of the block **308** allows the surgeon to assess offset, leg length, and the range of motion of the joint with the proposed implants in place before significant preparation of the bone has been done." Accordingly, the feature in the claims that relates to determining the

range of motion of the joint is captured by block **308** in FIG. 3, as further described in the specification at page 11, as noted above.

As to the second limitation, FIG. 2 includes block **214**, which is labeled "Determine Stability." The specification at page 10, lines 2-7, recites:

> the surgeon will confirm the stability of the joint in a block **214**. In the block **214**, the surgeon will manipulate the joint to confirm that the joint will not dislocate under normal activities and that the range of motion is acceptable. ... As part of this confirmation, the surgeon will look at the soft tissue surrounding the joint and also look at the potential for the reconstructed joint to dislocate.

Accordingly, the feature in the claims that relates to determining the stability of the joint is captured by block **214** in FIG. 2, as further described in the specification at page 10, as noted above.

For the reasons set forth above, applicant requests that the stated objection to the drawings be withdrawn.

REJECTION UNDER 35 U.S.C. §103(a): CARSON/SALEHI. Claims 1-5, 7, 8, 14, 15, 21-26, 28-32, 35, 41, 42, and 89-93 stand rejected as allegedly obvious over Carson *et al.* in combination with Salehi *et al.* Applicant respectfully traverses.

The Office action contends that Carson *et al.* teaches the claimed method apart from "the placement of the stem and use of the sagittal and coronal planes." The Office action further contends that Salehi *et al.* cures Carson *et al.* by disclosing various means for attaching bone implants, thus suggesting equivalent attachment means that the ordinary artisan would have employed in the method of Carson *et al.* *See* Office action at 4. However, Carson *et al.* additionally fails to disclose or suggest other elements of applicant's claimed invention, including, without limitation: (i) constructing intra-operatively a three-dimensional model of a ball and socket joint, and (ii) preparing the ball-containing limb to receive a stem using the three-dimensional model. In both defects, the common point is the three-dimensional model, with particularity provided regarding its making (intra-operatively using the surgical navigation system) and its use (for preparing the limb, *inter alia*).

The Office action's contended showing that Carson *et al.* presents an intra-operative model-constructing step stems from that patent's discussion of prior art methods identified there to be inferior. Office action at 2; Carson *et al.* at col. 4, ll. 12-13. The Office action cites *In re Gurley* (31 U.S.P.Q.2d 1130 (Fed. Cir. 1994)) in its argument to overcome applicant's assertion that Carson *et al.* teaches away from use of the inferior prior art methods. Among other significant drawbacks, applicant noted language from the Carson *et al.* patent that the prior art methods are "much slower, almost doubling operating room time and expense." Carson *et al.* at col. 4, ll. 39-45, *inter alia*. In *Gurley*, the applicant sought to distinguish a reference that disclosed a claimed element among alternative such elements, and taught that the element used in the *Gurley* applicant's invention was inferior to the recited alternatives. *Gurley* at 1132. The *Gurley* applicant argued that the reference taught away from its invention and should be viewed as a basis for surmounting the obviousness-based rejection. The Federal Circuit did not agree with the *Gurley* applicant.

The Office action appears to rely on *Gurley* for the proposition that just because something is inferior is no reason for the ordinary artisan to refrain from using it. Office action at 2. *Gurley*, however, holds that a reference cited as teaching away with respect to an obviousness rejection needs to be evaluated as to its nature to determine its relevance. *Gurley* at 1132 ("...the nature of the teaching is highly relevant, and must be weighed in substance."). In the factual context of the *Gurley* invention, which relates to a material for making printed circuits, the lack of criticality of the stated inferior material did not compel a conclusion that its inclusion could serve as a patentable distinction for a claim to a new composition of matter. *Gurley* at 1131. However, transposing that position to the context of the present invention, which relates to a surgical procedure that can result in significant harm to a patient, including potential lifelong detriment or death, one certainly hopes that even the routineer would be dissuaded from employing any procedure or material noted to be inferior. Office action at 2.

Indeed, applicant asserts that *Gurley* is an appropriate cite to support the position that the negative description of prior art methods set forth in the Carson *et al.* patent constitutes a "teaching away" scenario by which to avoid that reference under Section 103: Any surgeon, even one of ordinary skill, would reasonably avoid using known inferior materials or methods in conducting surgery on a human. In particular, the passage in Carson *et al.* relating to the prior art

and its drawbacks serves to discourage one from pursuing a method step of digitizing points with respect to a joint. In contrast to the prior art discussed therein, the Carson *et al.* patent states that the "[s]ystems and processes according to the present invention represent significant improvement...." Carson *et al.* at col. 4, ll. 12-13. The Carson *et al.* patent clearly does not teach or suggest using the methods identified as inferior prior art. *See* Carson *et al.* at col. 4, ll. 12-45.

Accordingly, applicant's assertion that Carson *et al.* teaches away from the present invention and thus supports the nonobviousness of the present invention remains applicable.

What is taught by the Carson *et al.* patent is summarized as nine steps at column 3, line 16 to column 4, line 3 thereof. None of the nine steps recited teach or suggest constructing a three dimensional model of a ball and socket joint, or of any sort of a joint or any sort of a model. Nor do any of the nine steps recited teach or suggest preparing a ball-containing limb to receive a stem using the three dimensional model. Indeed, the Carson *et al.* patent as a whole neither discloses nor suggests either of elements (i) or (ii) of applicant's invention identified above, which are required limitations of each and every pending claim.

Also compelling as a reason to discount the relevance of the Carson *et al.* patent, the first step provided there is to "[o]btain appropriate images such as fluoroscopy images of appropriate body parts...." Carson *et al.* at col. 3, ll. 16-17. The claimed method of the present invention does not require images, fluoroscopic or otherwise; and, as amended, the claimed method does not require any scan, which is the source of the Carson *et al.* images. Neither does the present invention provide a method that requires exposing the patient and operating room personnel to additional radiation, as noted above in the discussion of the pending claims.

The Office action notes a passage in the Carson *et al.* patent (at col. 4, ll. 21-22) that discusses digitizing points with respect to defining knee "geometries". Office action at 2. The following phrase in the Office action states that "...it is unclear to the examiner what applicant is envisioning the term 'modeling' to encompass, if the passage at lines 21-22 is to be excluded therefrom." *Id.* In order to better understand the position recited in the Office action, which is evidently based on the Examiner's personal knowledge, applicant hereby requests the Examiner to provide an explanation by affidavit as to his personal knowledge by which he concluded that the cited passage of the Carson *et al.* patent describes modeling of a joint that could be used in the context of the present invention. 37 C.F.R. §1.104(d)(2).

The Salehi *et al.* patent cannot cure the deficiencies of the Carson *et al.* patent. The Office action recites that "Salehi et al teach the equivalence of stems and other means for attaching implants to the bones they are to be mounted on." Office action at 4. Applicant respectfully submits that the cited contribution of the Salehi *et al.* patent is irrelevant as a cure to the defects of the primary reference, as noted above.

Accordingly, applicant requests that the Section 103 rejections based on the combination of the Carson *et al.* and Salehi *et al.* patents be reversed.

REJECTION UNDER 35 U.S.C. §103(a): CARSON/DIGIOIA. Claims 1-12, 14-39, 41-53, and 89-93 stand rejected as allegedly obvious over Carson *et al.* in combination with DiGioia *et al.* Applicant respectfully traverses.

The Office action presents the DiGioia *et al.* reference as teaching the present invention "except for the specific recitation of producing a three-dimensional model of the joint per se." Accordingly, DiGioia *et al.* neither teach nor suggest construction of a three-dimensional model of a ball and socket joint constructed intra-operatively. It necessarily follows that DiGioia *et al.* does not teach or suggest preparation of a limb to receive a stem using the three-dimensional model either. As fully recited above with respect to the Carson *et al.*/Salehi *et al.* combination, neither does Carson *et al.* teach or suggest these two elements, which are described in all currently pending claims.

Applicant requests that the rejections predicated on the combination of Carson *et al.* and DiGioia *et al.* be reversed.

REJECTION UNDER 35 U.S.C. §103: [CARSON/SALEHI OR CARSON/DIGIOIA] AND GUSTILO. Claims 13 and 40 stand rejected as allegedly obvious over Carson *et al.* in combination with Salehi *et al.* or Carson *et al.* in combination with DiGioia *et al.*; and further in view of Gustilo *et al.* Applicant respectfully traverses.

As argued above, neither Carson *et a*l. in combination with Salehi *et al.* nor Carson *et al.* in combination with DiGioia *et al.* teach or suggest at least two limitations of all pending claims. Those two missing limitations are (i) constructing intra-operatively a three-dimensional model of

a ball and socket joint and (ii) preparing a limb to receive a stem using the three-dimensional model. Both of these limitations are included in claims 13 and 40.

The Office action contends that the addition of the disclosure of Gustilo *et al.* to the aforementioned pairs of references renders obvious the inventions of claims 13 and 40. The Office action states that "Gustilo *et al.* teaches that relating the depth of the reaming to the depth of the medial wall maximizes the stability of the prosthesis." Office action at 5. Applicant respectfully disagrees. While it is generally the case that a surgeon intends to "ream the acetabulum without violating the medial acetabular wall", the Gustilo *et al.* invention provides "an acetabular cup prosthesis that accommodates numerous shapes and sizes of defects while at the same time minimizing the amount of bone that must be removed." Gustilo *et al.* at col. 1, ll. 29-30 and 52-54. Gustilo *et al.* further teach that the invention "discloses a means for stabilizing the prosthesis with an extension that is attached to the prosthesis and anchored to the bone" (*Id.* at col. 1, ll. 55-57); *i.e.*, Gustilo *et al.* teaches a different way to achieve a stable prosthesis than that attributed to claim 13 or 40 by the Office action. Accordingly, even if the Office action was correct in describing the teachings or suggestions included in the aforementioned pairs of cited references, then neither of those combinations with Gustilo *et al.* would have resulted in the invention of claim 13 or 40.

What is not included in Gustilo *et al.* is any teaching or suggestion relating to (i) constructing intra-operatively a three-dimensional model of a ball and socket joint and (ii) preparing a limb to receive a stem using the three-dimensional model. Accordingly, the recited combinations of references cannot result in the present invention as described by any of the currently pending claims.

PROVISIONAL REJECTION UNDER NON-STATUTORY DOUBLE PATENTING DOCTRINE. All pending claims stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting. As noted in the prior Amendment A of June 12, 2006, because no claims have been found allowable in either the present application or in Serial No. 10/732,553, an appropriate terminal disclaimer will be prepared and submitted in due course.

CONCLUSION. In view of the remarks set forth herein, applicant respectfully submits that the pending claims are allowable and request that they be passed for allowance. If contacting the undersigned would help expedite the prosecution of this application, the Examiner is invited to make contact at the phone number set forth below.

DEPOSIT ACCOUNT AUTHORIZATION. The Commissioner is hereby authorized to charge any deficiency in any amount enclosed or any additional fees that may be required during the pendency of this application under 37 C.F.R. §1.16 or §1.17, except issue fees, to Deposit Account No. 50-1903.

Respectfully submitted,

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